\_ 28 AOT '95 15:11 ETHYPHARM ST CLOUD 41 12 17 30

P.14/16

BELMAC/ETHYPHARM RJ - 3/07/1995

# ANNEX A TO THE AGREEMENT BETWEEN BELMAC AND ETHYPHARM S.A. (SPAIN)

#### PRODUCTS MANUFACTURED BY ETHYPHARM

(additional products may be added to this initial list by separate addendum to this Agreement).

28 AOT '95 15:11 ETHYPHARM ST CLOUD 41 12 17 30 BELMAC/ETHYPHARM RJ - 3/07/1995

P.15/16

# ANNEX B TO THE AGREEMENT BETWEEN BELMAC AND ETHYPHARM S.A. (SPAIN)

# DETAILS OF INVESTMENT MADE BY ETHYPHARM (as per Whereas 2)

- 1) Investment
- 2) Equipment
- 3) Documentation transmitted to BELMAC.

28 AOT '95 15:11 ETHYPHARM ST CLOUD 41 12 17 38

P.16/16

BELMAC/ETHYPHARM RJ-3/07/1995

# ANNEX C TO THE AGREEMENT BETWEEN BELMAC AND ETHYPHARM S.A. (SPAIN)

<u>DETAILS OF PREMISES LEASED BY BELMAC TO ETHYPHARM (as per Clause 2.4)</u>

<<< Page 1 >>>

DIRECTORS

OF MEETING OF THE BOARD

Of

#### BENTLEY PHARMACEUTICALS, INC.

A meeting of the Board of Directors of Bentley Pharmaceuticals, (the "Company") was held on October 8, 1996. Members present at the Company's offices in Tampa were:

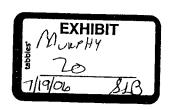
> James R. Murphy Robert M. Stote Michael D. Price Randolph W. Arnegger Charles L. Boiling Doris E. Wardell

Also present, at the request of the Company, were the Company's legal counsel, Jordan
Horvath of Parker Chapin Flattau & Klimpl, LLP, and Barry Blank of Coleman and Company Securities, Inc.

 $\,$  Mr. Murphy acted as Chairman of the meeting and Mr. Price, at the request of the Chairman, acted as Secretary of the meeting.

Mr. Murphy called the meeting to order and indicated that the first item of business was to approve the minutes of the Board of Directors' meeting held on June 14, 1996. After
discussion regarding the minutes and a minor clarification, upon motion duly made, seconded, and unanimously carried, it was

RESOLVED, that the minutes of the Board of Directors' meeting held on June 14, 1996 are hereby approved.



<<< Page 2 >>>

Mr. Murphy then asked Mr. Price to present a Financial Report on the Company and,

in response, Mr. Price presented draft financial statements as of

and for the eight months ended
August 31, 1996, explaining the changes from the prior year and

respect to financial matters. Mr. Price then compared the actual f'mancial results to the budget,

and explained the variances. Messrs. Blank and Arnegger questioned the strategy of continuing

to market the disposable linens via Belmac Healthcare Corporation,

commenting that this line
does not strategically fit with the balance of the Company's
operations, is minute in comparison

to the other divisions, and does not contribute materially to the bottom line. Messrs. Price and

Stote disagreed with the recommendation to divest Belmac Healthcare's disposable linen line,

stating that sales are growing, are profitable, and give the Company a presence in the U.S.

market. Mr. Price stated that until such time that a material U.S. acquisition is consummated,

these activities contribute positively to the bottom line and should not be eliminated. Ms.

Wardell then agreed, indicating that the subject should be tabled until circumstances change.

The subject then turned to the pros and cons of closing the Company's U.S. operations entirely and moving the headquarters to Europe. Mr. Price presented

corporate office bum rate, which indicated that the monthly burn

rate was approximately \$260,000, including interest on the Debentures, and explained that

serve to transfer the majority of such expenses to Europe, because a relatively immaterial portion are related to occupancy - the vast majority being administration,

legal, accounting, SEC

compliance, and insurance-related, which would exist whether the Company's headquarters was

in the United States or Europe.

<<< Page 3 >>>

due diligence, should the

transaction not be consummated.

Mr. Murphy then reported on the activities in Spain, including a current status report, a summary of ongoing negotiations and future projections.

Messrs. Murphy and Price then provided an update of activities in France, including the status of discussions being held with Marsing & Company regarding their interest in acquiring
Chimos/LBF. Messrs. Murphy and Price indicated that Massing is conducting its due diligence
and that management would report back to the Board with a
status report and will request
approval from the Board prior to concluding any transaction

Mr. Murphy then indicated that the next topic of discussion was a status report on acquisition possibilities, including Fidia, Conrex, Flemington and MEI. Regarding Fidia, an Italian company, Mr. Murphy reviewed the components, history, products and the need for careful due diligence. Discussion then centered around the cost of proper due diligence, which is expected to exceed \$100,000, and the wisdom of spending such a large amount of the Company's resources at this time. Mr. Price responded that the Company had to move forward and that it could not afford to remain status quo. He continued by stating that it is critical to the future of the Company that it grow by acquisition and not continue to burn cash at the rate of \$260,000 per month. The suggestion was made to request that Coleman & Company indemnify the Company for the cost of due diligence in the event that such due diligence uncovers issues that prevent an acquisition. Mr. Blank was asked to excuse himself and contact

Coleman to inquire about possible indemnification for the costs of

<<< Page 4 >>>

Dr. Stote presented information with respect to Fidia's products under development and the potential benefits and risks of acquiring Fidia. Mr. Blank returned to the meeting and relayed the results of his conversation with Coleman, whereby Coleman indicated that it could not indemnify Bentley for the cost of Fidia due diligence, but would

ask the Italians to consider such an indemnification. However, it was agreed that Messrs. Murphy and Price were

authorized to initiate a preliminary level of discussions and meetings in order to determine whether Fidia was a viable acquisition candidate.

Mr. Murphy then presented another possible acquisition to the Board, namely the technology of Conrex Pharmaceutical. He summarized the company's history, products, technology, etc. and informed the Board that discussions were under way. Mr. Murphy concluded by indicating that the Company will not enter into a definitive agreement for the acquisition of Conrex' technology without prior approval of the

Mr. Blank then suggested to the Board that they consider declaring a  $10\ %$  stock dividend. Mr. Murphy asked Mr. Blank to compare the effect of a 10% stock dividend to the effect of offering a discount to holders of the Class A Warrants for early exercise. Mr. Blank responded that it is possible to do both, but that the Company should begin with the 10% stock dividend.

Redacted

Board.

<<< Page 5 >>>

Redacted

Board tha

Mr. Price informed the

Articles of Incorporation allow stock dividends to Common

shareholders when in arrears on

payment of preferred stock dividends. Discussion proceeded regarding perception of the

Company and the pros and cons of declaring a stock dividend. The subject of a stock dividend

was then tabled until later in the meeting.

Mr. Murphy then asked Mr. Price to give a report on the

Walter Light issue, whereupon
Mr. Price informed the Board members that an agreement had been reached with Mr. Light

whereby he agreed to sign a hold harmless agreement with the Company and accept, as full

settlement of his claim, warrants to purchase 350,000 shares of the Company's Common Stock,

at \$2.50 per share, which was the market price on the date that the

agreement was reached. Mr.

Price asked the members of the board to ratify the agreement with Mr. Light and upon motion

duly made, seconded and unanimously carded, it was

RESOLVED, that the agreement between Mr. Walter Light and the Company, dated August 27, 1996, whereby Mr. Light

agreed to accept as full settlement for his claims, warrants to

purchase

350,000 shares of the Company's Common Stock, at the market price on that date of \$2.50 per share, exercisable for five

years, is hereby ratified in its entirety.

Mr. Murphy then asked the Board to take a short recess in order for the Compensation

Committee to convene. All members of the Board agreed and the meeting was recessed. Upon

the conclusion of the Compensation Committee meeting, the meeting of the Board of Directors was reconvened. Redacted

was agreed that Mr. Price would provide all of the necessary information with respect to outstanding stock options, their expiration dates, and exercise prices to the Compensation Committee for them to consider.

iMr. Murphy then provided a brief summary of other possible acquisition/JV candidates including Flemington Pharmaceutical, Fleet/Casen-Spain and MEI. No action was taken with respect to these matters.

iMr. Boiling excused himself from the Board meeting at this time in order to avoid missing his return flight.

Members of the Board were then provided with a brief update of pending or recently

resolved legal issues (copy attached as Exhibit A).

Members of the Board were then provided with an abbreviated Business Plan, which sets

forth the Mission Statement and objectives for 1996 and 1997 (copy attached as Exhibit B).

<<< Page 7 >>>

Mr. Price then explained that the 1994 Stock Option Plan, which was due to expire on September 8, 1996, was extended for two additional years, until September 8, 1998, by the

management of the Company, and reviewed the purpose of the 1994

Plan. After discussion,

upon motion duly made, seconded and unanimously carded, it was

RESOLVED, that the action taken by management of the Company to extend the life of the 1994 Stock Option Plan to September 8, 1998 is hereby ratified.

As a final item of business, Mr. Price asked the board members to authorize him to file
Listing Applications with the American Stock Exchange and the

Pacific Stock Exchange to list
its shares of Common Stock for issuance with respect to 1,500,000 shares of Common Stock

underlying the options granted to the Company's Executive Officers

on April 19, 1996 and approved by the Company's stockholders at the Annual Meeting of Stockholders on June 14,

1996; 200,000 shares of Common Stock underlying the 200,000

incremental warrants granted

to Mr. Light; 120,000 shares of Common Stock underlying the Company's 1994 Stock Option

Plan; 25,000 shares of Common Stock underlying warrants granted to Ronald Trahan and

Associates; and to authorize him file a registration statement on Form S-3 in order to register such shares of Common Stock and any other shares of Common Stock

the Company deems appropriate for resale, whereupon, upon motions duly made, seconded and unanimously carried, it was

RESOLVED, that the officers of the Company are hereby authorized by the Company to make applications to the

American

Stock Exchange and the Pacific Stock Exchange for the

listing of

<<< Page 8 >>>

up to 1,845,000 shares of Common Stock; and it was further RESOLVED, that such officers are hereby authorized and directed to sign said applications and any listing agreements or documents required by said Exchanges in connection therewith and to make such changes in any of same as may be necessary to conform with the requirements for listing, ant to appear (if requested) before officials of such Exchanges; and it was further RESOLVED, that the foregoing shares of Common Stock be, and they hereby are, duly authorized for issuance and when issued and delivered in exchange for payment therefor in accordance with the terms described above, such shares shall be fully paid and nonassessable shares of Common Stock of the Company and the holder thereof shall not be liable for any calls or assessments thereon or for any payment in respect thereof; and it was further RESOLVED, that the officers of the Company are authorized to file a registration Statement on Form S-3 and file such registration Statement with the Securities and Exchange Commission in order to register resales of shares of its Common Stock either held by. or underlying options or warrants held by, the Company's Executive Officers (1,500,000 shares); Walter Light (350,000 shares); Ronald Trahan & Associates (25,000 shares); Dr. Jeff Harris (6,400 shares); and it was further RESOLVED, that such officers are hereby authorized by the Company to take all other action and to execute and deliver all other agreements and instruments and to affix the Company's seal thereto if required, that may be necessary or appropriate to carry out the purpose and intent of the foregoing resolutions. Mr. Price informed the Board members that Dr. Harris acquired

the 6,400

Company's Common Stock referred to above, which bear a restrictive legend, from Ranald

Stewart, the Company's former Chairman, via a judgement and garnishment related to litigation

that he brought against Ranald Stewart in a legal matter unrelated to the Company.

Before adjournment, the Board returned to the matter of a stock dividend. Mr. Blank

delayed

it

strongly recommended that the Board authorize a 10% stock dividend. Mr. Price stated that he was uncomfortable voting on such a matter without the benefit of some guidance from other knowledgeable sources such as investment bankers, brokers, shareholders, etc. He suggested
that he would like to receive input from Jerry Bertner or Michael
Gardner before making a
decision. The meeting was recessed briefly while Messrs. Bertner and Gardner were consulted and then reconvened. Messrs. Murphy and Price relayed the responses and Gardner, who were cautiously supportive of the concept, but warned of the risks. After additional discussion, upon motion duly made, seconded and unanimously carded, it was

RESOLVED, that the Board of Directors hereby authorizes the declaration of a 10% stock dividend to its Common shareholders, the dates of record and issuance of which shall be determined by the Board at a later date, and which stock dividend may be or abandoned by the Board at any time in the future should become advisable to do so.

There being no further business to come before the meeting, upon motion duly made seconded, and unanimously carded, the meeting was adjourned.

D. Price, Secretary

<<< Page 10 >>>

BENTLEY

PHARMACEUTICALS,

INC.

SUMMARY OF LEGAL ISSUES

Redacted

LEGAL ISSUF~, Continued

Redacted

<<< Page 12 >>>

#### CORPORATE

#### DESCRIPTION

Bentley Pharmaceuticals, Inc. is an international pharmaceutical and healthcare company engaged in manufacturing, marketing, and distribution of ethical pharmaceuticals, orphan drugs, biotech products, and fine chemicals in France and Spain, and limited research & development and distribution of disposable medical products in the United States. The strategic focus of the organization consists of a combination of short and long term objectives to achieve near term profitability and continued growth into the new century.

#### MISSION

Because of the stringent and costly regulatory requirements a new pharmaceutical product typically requires \$100-200 million and 7-10 years of effort. Bentley is a small international pharmaceutical company which will no longer research and development of New Chemical Entities (NCE's) without the support of a collaborative partner capable of absorbing such risks. On the contrary we have defined our mission to be a limited-research based pharmaceutical company with emphasis on generics, new drug delivery systems and Improved Chemical Entities (ICE's).

Our primary focus for the next two years will be to increase shareholder value by concentrating on critical mass in revenues and the bottom-line. To achieve this objective it is necessary that we build upon our portfolio of products by way of:

acquisition of currently marketed products

development of a formal in-licensing policy

submission of additional regulatory dossiers for new economically
important generics (e.g. Prozac, and Questran)
advancing our position drug delivery systems
teaming in R&D collaborations to out-license products

Equally important is the initiation of longer-term strategies (three to five years). By utilizing a strategy to improve the efficacy and delivery of existing products based upon

new drug delivery systems, these objectives can be economically achieved within a

reasonable amount of time. This will allow us to enter a market that has already been

established building upon many years' history of safety and efficacy yet deriving

equivalent proprietary benefits through the patent protection of delivery systems.

Examples of these systems include:

Spain

- · microgranulation and microencapsulation technology in
- transdermal patch technology of Alphanon®
- transformation to amorphous forms as Biolid®

acquired

transdermal gels, creams, and ointments
Other delivery systems obtained under license or

Spain

· Obtain U.S. FDA GMP certification for manufacturing in

<<< Page 13 >>>

**Objectives** for the balance 1996

Listed below are the primary short-term objectives for the balance of

1996. Acheivement of 6 of the 12 would certainly be noticable and stabilize Bentley assuring a solid foundation for entering calendar year 1997

- 1. Complete the development and obtain regulatory approval for a topical Diclofenac in Spain (equivalent to Ciba's Voltaren) emphasizing our commitment to drug delivery systems and documenting that new products can be developed without the expenditure of large amounts in R&D nor an extensive period of time in development.
- 2. Locate and negotiate an improved sustained release product based upon externally developed drug delivery technology for exclusive in-licensing into
- 3. Signing of contract to promote well recognized generics for a major multinational pharmaceutical company.
- 4. Obtain exclusive marketing rights to launch a new product on behalf of a major multinational pharmaceutical company.
- 5. Establishment of a research collaboration to advance our R&D pipeline products. Products available for collaboration include: Biolid, Alphanon, Microgranulated omeprazole, and possibly in feminine healthcare products.
- 6. Identify and begin negotiations with a company possessing patented drug delivery technologies that could provide a mid and long-term stream of products as well as an avenue to license products to multinational companies providing immediate milestone payments and future royalties.
  - 7. Expand product lines into other healthcare markets in Spain
- $\theta$ . Identify potential candidates and advance discussions at least through the stage of signing a confidentiality agreement and a letter of intent with those who would have interest in the purchase of Chimos.
- 9. Identify an acquisition/merger candidate and advance discussions at least through the stage of signing a confidentiality agreement and a letter of intent for expansion in the European Union and/or the U.S. market.
- 10. Obtain additional contract manufacturing contracts and/or joint ventures in Spain to assure continued growth through 1997.
- 11. Obtain foreign registrations for Spanish products in other Spanish speaking countries continuing to build the export division. (specifically Latin and South America)
- 12. Acheive the first solidly profitable year in Spain by closing out the 1995 year with pretax net earnings of at least .5 million US dollars.

<<< Page 14 >>>

Objectives for 1997

Reposition the direction of the company by establishing a highly visible identity as a drug delivery organization.

Establish an off balance sheet company to engage in limited research in drug delivery thereby establishing a pipeline of products, avenue for milestone payments, and future royalty stream.

Obtain several R&D collaborations with multinationals to develop new products based upon drug delivery.

Consummate the acquisition of a company in the U.S.

Consummate the acquisition of products or company in Europe allowing expansion to other EU nations beyond Spain.

Financial

Projections

1996

1997

1998

Revenues 24 million

35 million

22 million

Operations

< (0.9) mil.

After Debt Service (2.7) mil.

0.1 million 1.5 million

Events That Would Significantly Alter the Business Plan

Based upon the current search and early-stage negotiations, it appears that we have

opportunities to expand in Europe as well as in the U.S. The successful completion of any

or all the below acquisitions would significantly alter the mission as well as the financial projections of Bentley.

1. Conrex has patented transdermal and transmicosal enhancer technology based upon

a GRAS designated chemical. The potential applications are immence including the

delivery of 5-FU, methotrexate, Ibuprofen, Diclofenac, insulin, calcitonin, ergotamine, estrogen, progesterone, testosterone, etc.

We would intend to collaborate with other companies in the R&D and licensing of these

products. They have already had discussions with a large number of companies who

recognize the potential including Boots and Genta/Jago who are currently evaluating

products. We know that Procter and Gamble, Bausch and Lomb, Pfizer, Sandoz, McNeil,

Wyeth, Schering (Berlex), and Rhone Poulenc/ Dermick are currently seeking this type of technology.

<<< Page 15 >>>

We would acquire the assets of this corporation and in the event limited research is required by Bentley we would consider spinning this company off into a shell corporation either formed by us or acquired so that we could raise funds independently in an off-balance sheet manner. Thereafter when the company becomes profitable, it would be re-acquired by Bentley in a stock swap. The reason for employing this strategy is to avoid the losses associated with basic R&D activities. This technique has been quite

successful and commly used by Alza, Sepracor and Genzyme corporations. 2. Flemington Pharmaceuticals possess patented technology for

rapid onset of therapeutics. The technology uses a bite capsule that delivers through the musocal membrane and the first products have been developed through Phase I. Since the applications involve products with an established history of safety and efficacy, the

expense of development and the regulatory paths are minimal. They will be signing a major licensing agreement within the near future (60 days).

I have met with Flemington and there is interest in advancing the discussions to the next level since they are looking at the possiblity of going public at this stage. The acquisition of Conrex technology will make Bentley a more interesting candidate because Flemington have also attempted to merge with Conrex over the past year believing there are a number of.

3. Fidia Pharmaceuticals is a sizable Italian company with annual revenues of approximately \$65 million. Acquisition of Fidia would result in additions to both our domestic and European operations including 870 patents on a worldwide basis, international distribution, a limited US presence but a number of pending US registrations, a tremendous opportunity to out-license a number of products.

The proforma financials have not yet been established but the basic assumption is that the combined companies would be profitable from the onset and a sufficient amount of capital would be in place to consummate the deal and continue the development of the R&D pipeline.

We envision a major change in R&D philosophy. To date, Fidia has individually funded all research electing to avoid licensing opportunities even though a number of sizable organizations have made offers to collaborate. By entering into R&D collaborations and licensing agreements they could save a tremendous amount of funds which would immediately be recognized as improvement in the bottom line.

1996 1997 1998

> Revenues w/Fidia 90 mil 100 mil Royalty income 2 mil 6 mil

4. Shire Pharmaceuticals Group PIc. is a growing U.K. company with revenues of approximately \$35 million. The company is profitable and has cash

approximately \$40 million. The primary focus on the development, licensing and marketing of drugs in the specialty areas of metabolic bone diseases and the central nervous system.

Shire has hired The Wilkerson Group (div. of IBM) to find a merger candidate in the
United States. Shire has its own sales force in the U.K. and Ireland and distributes
through others in N. Africa, Mediterranean contries, middle and far east. The ideal
merger candidate, as described to us, would be a U.S. based organization that is marginly
profitable or at breakeven.

# ACUERDO DE CONFIDENCIALIDAD

Considerando que D. Clemente González Azpeitia con D.N.I. 2009837 y domicilio en Av. La Loma, 27 TORRELODONES (Madrid) empleado de la empresa Laboratorios Belmac, S.A., tiene, debido al acuerdo de colaboración alcanzado entre Belmac y Ethypharm, acceso a información confidencial que pertenece a Ethypharm.

#### POR CONSIGUIENTE:

- 1. D. Clemente González Azpeitia se compromete formalmente a no divulgar a nadie, salvo autorización escrita de Ethypharm, las citadas informaciones confidenciales, ni utilizarlas por su cuenta o para terceros, excepto para el trabajo que Belmac y Ethypharm le encomiendan derivado de la cooperación de ambas compañías.
- 2.- La información confidencial cubre todo lo referente a: especificaciones de fabricación y control, protocolos de fabricación y control y procedimientos de fabricación y control.

En Madrid, a VEINIE de FEBRINO de 1996

Leído y aprobado (en manuscrito)

Fdo.: Clemente González Azpeitia

# **CONFIDENTIALITY AGREEMENT**

Considering that D. Clemente González Azpeitia with D.N.I 2009837 and address in Av. La Loma, 27 TORRELODONES (Madrid) employee of the company Laboratorios Belmac, S.A., has, as a consequence of the collaboration agreement reached between Belmac and Ethypharm, access to confidential information owned by Ethypharm.

# THEREFORE:

- 1. Mr. Clemente González Azpeitia formally commits not to disclose to anyone, with the exception of having a written authorization from Ethypharm, the mentioned confidential information, nor will he use it for himself or for third parties, except for the work that Belmac and Ethypharm request of him related to the collaboration between both companies.
- 2. The confidential information covers all that is related to: manufacturing and control specifications, manufacturing and control protocols and manufacturing and control procedures.

In Madrid, 20 February 1996.

Read and approved (in handwriting)

[Signature]

Signed: Clemente González Azpeitia

# ACUERDO DE CONFIDENCIALIDAD

	Cons	siderando que	D. JUA	N CARLOS	ASENSIO ASENS	iocon		
	D.N.	.I. <u>174375810</u>	y domicil	io en	ZARAGOZA			
						e, debido al acuerdo		
		olaboración alcanzado entre Belmac y Ethypharm, acceso a información						
		idencial que p						
		• •						
<b>A</b>								
<b>(3)</b>	POF	R CONSIGUI	ENTE:					
<b>、</b>	1	Ethypharm, su cuenta o	e a no div las citada para terce	ulgar a nac as informac eros, excep	die, salvo autorizac	es, ni utilizarlas por jue Belmac y		
	2	especificacio	ones de fa	abricación	pre todo lo referent y control, protocol- pricación y control.	e a: os de fabricación y		
		•						
	En M	Aadrid, a	20	de	FEBRERO	de 1996.		
	Leíd	o y aprobado	(en manu	scrito)				
		A Curt		Apeula Fdo.:				

# **CONFIDENTIALITY AGREEMENT**

Considering that D. Juan Carlos Asensio Asensio with D.N.I 174375810 and address in Zaragoza, employee of the company Laboratorios Belmac, S.A., has, as a consequence of the collaboration agreement reached between Belmac and Ethypharm, access to confidential information owned by Ethypharm.

# THEREFORE:

- 3. Mr. Juan Carlos Asensio Asensio formally commits not to disclose to anyone, with the exception of having a written authorization from Ethypharm, the mentioned confidential information, nor will he use it for himself or for third parties, except for the work that Belmac and Ethypharm request of him related to the collaboration between both companies.
- 4. The confidential information covers all that is related to: manufacturing and control specifications, manufacturing and control protocols and manufacturing and control procedures.

In Madrid, 20 February 1996.

Read and approved (in handwriting)

Signed:

[Signature]

# ACUERDO DE CONFIDENCIALIDAD

POF	CONSIGUIENTE:
1	D ANTONIO CABODEVILLA ILINCHETA se compre formalmente a no divulgar a nadie, salvo autorización escrita de Ethypharm, las citadas informaciones confidenciales, ni utilizarla su cuenta o para terceros, excepto para el trabajo que Belmac y Ethypharm le encomiendan derivado de la cooperación de ambas compañías.
2	La información confidencial cubre todo lo referente a: especificaciones de fabricación y control, protocolos de fabricacion y procedimientos de fabricación y control.

# **CONFIDENTIALITY AGREEMENT**

Considering that D. Antonio Cabodevilla Ilincheta with D.N.I 18211833L and address in Zaragoza, employee of the company Laboratorios Belmac, S.A., has, as a consequence of the collaboration agreement reached between Belmac and Ethypharm, access to confidential information owned by Ethypharm.

### THEREFORE:

- 5. D. Antonio Cabodevilla Ilincheta formally commits not to disclose to anyone, with the exception of having a written authorization from Ethypharm, the mentioned confidential information, nor use it for himself or for third parties, except for the work that Belmac and Ethypharm request of him related to the collaboration between both companies.
- 6. The confidential information covers all that is related to: manufacturing and control specifications, manufacturing and control protocols and manufacturing and control procedures.

procedures.	
In Madrid, 20 February 1996.	
Read and approved (in handwriting)	

Signed:

[Signature]

POF	CONSIGUIENTE:	
1	D. JOSE LUIS MONTERDE MAO formalmente a no divulgar a nadie, Ethypharm, las citadas informacion su cuenta o para terceros, excepto Ethypharm le encomiendan derivac compañías.	, salvo autorización escrita de nes confidenciales, ni utilizarla para el trabajo que Belmac y
2	La información confidencial cubre especificaciones de fabricación y control y procedimientos de fabric	control, protocolos de fabricac
	ſadrid, a <u>20</u> de <u>гев</u>	RERO de 199

Fdo.:

# **CONFIDENTIALITY AGREEMENT**

Considering that D. José Luis Monterde Maorad with D.N.I 17223752H and address in Zaragoza, employee of the company Laboratorios Belmac, S.A., has, as a consequence of the collaboration agreement reached between Belmac and Ethypharm, access to confidential information owned by Ethypharm.

#### THEREFORE:

- 7. D. José Luis Monterde Maorad formally commits not to disclose to anyone, with the exception of having a written authorization from Ethypharm, the mentioned confidential information, nor use it for himself or for third parties, except for the work that Belmac and Ethypharm request of him related to the collaboration between both companies.
- 8. The confidential information covers all that is related to: manufacturing and control specifications, manufacturing and control protocols and manufacturing and control procedures.

In Madrid, 20 February 1996.

Read and approved (in handwriting)

Signed:

[Signature]

EXHIBIT B

# ENERTHEY PHATEMACEUM CALSUMC

### CORPORATE DESCRIPTION

Bentley Pharmaceuticals, Inc. is an international pharmaceutical and healthcare company engaged in manufacturing, marketing, and distribution of ethical pharmaceuticals, orphan drugs, biotech products, and fine chemicals in France and Spain, and limited research & development and distribution of disposable medical products in the United States. The strategic focus of the organization consists of a combination of short and long term objectives to achieve near term profitability and continued growth into the new century.

# MISSION

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Our primary focus for the next two years will be to increase shareholder value by concentrating on critical mass in revenues and the bottom-line. To achieve this objective it is necessary that we build upon our portfolio of products by way of:

- · acquisition of currently marketed products
- · development of a formal in-licensing policy
- submission of additional regulatory dossiers for new economically important generics (e.g. Prozac, and Questran)
- · advancing our position drug delivery systems
- teaming in R&D collaborations to out-license products

Equally important is the initiation of longer-term strategies (three to five years). By utilizing a strategy to improve the efficacy and delivery of existing products based upon new drug delivery systems, these objectives can be economically achieved within a reasonable amount of time. This will allow us to enter a market that has already been established building upon many years' history of safety and efficacy yet deriving equivalent proprietary benefits through the patent protection of delivery systems. Examples of these systems include:

- · microgranulation and microencapsulation technology in Spalin
- transdermal patch technology of Alphanon®
- · transformation to amorphous forms as Biolid®
- · transdermal gels, creams, and ointments
- Other delivery systems obtained under license or acquired:
- Obtain U.S. FDA GMP certification for manufacturing in Spain

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#### Objectives for the balance of 1996

Listed below are the primary short-term objectives for the balance of 1996. Acheivement of 6 of the 12 would certainly be noticable and stabilize Bentley assuring a solid foundation for entering calendar year 1997.

- 1. Complete the development and obtain regulatory approval for a topical Diclofenac in Spain (equivalent to Ciba's Voltaren) emphasizing our commitment to drug delivery systems and documenting that new products can be developed without the expenditure of large amounts in R&D nor an extensive period of time in development.
- 2. Locate and negotiate an improved sustained release product based upon externally developed drug delivery technology for exclusive in-licensing into Spain.
- 3. Signing of contract to promote well recognized generics for a major multinational pharmaceutical company.
- 4. Obtain exclusive marketing rights to launch a new product on behalf of a major multinational pharmaceutical company.
- 5. Establishment of a research collaboration to advance our R&D pipeline products. Products available for collaboration include: Blolid, Alphanon, Microgranulated omeprazole, and possibly in feminine healthcare products
- 6. Identify and begin negotiations with a company possessing patented drug delivery technologies that could provide a mid and long-term stream of products as well as an avenue to license products to multinational companies providing immediate milestone payments and future royalties.
- 7. Expand product lines into other healthcare markets in Spain
- 8. Identify potential candidates and advance discussions at least through the stage of signing a confidentiality agreement and a letter of intent with those who would have interest in the purchase of Chimos.
- Identify an acquisition/merger candidate and advance discussions at least through the stage of signing a confidentiality agreement and a letter of intent for expansion in the European Union and/or the U.S. market.
- 10. Obtain additional contract manufacturing contracts and/or joint ventures in Spains to assure continued growth through 1997
- 11. Obtain loreign registrations for Spanish products in other Spanish speaking countries continuing to build the export division. (specifically Latin and South America)
- 12. Acheive the first solidly profitable year in Spain by closing out the 1995 year with pretax net earnings of at least .5 million US dollars:

#### Objectives for 1997

Reposition the direction of the company by establishing a highly visible identity as a drug delivery organization.

Establish an off balance sheet company to engage in limited research in drug delivery thereby establishing a pipeline of products, avenue for milestone payments, and future royalty stream.

Obtain several R&D collaborations with multinationals to develop new products based upon drug delivery.

Consummate the acquisition of a company in the U.S.

Consummate the acquisition of products or company in Europe allowing expansion to other EU nations beyond Spain.

Financial Projections

	1996		199	7	199	8
Revenues	22 m	illion	24	million	35	million
Operations	< (0.	9)mil.				
After Debt Se	ervice (2.	.7) mil.	0.1	million	1.5	million

#### Events That Would Significantly Alter the Business Plant

Based upon the current search and early-stage negotiations, it appears that we have opportunities to expand in Europe as well as in the U.S. The successful completion of any or all the below acquisitions would significantly after the mission as well as the financial projections of Bentley.

1. Conrex has patented transdermal and transmucosal enhancer technology based upon a GRAS designated chemical. The potential applications are immence including the delivery of 5-FU, methotrexate, Ibuprofen, Diclofenac, insulin, calcitonin, ergotamine, estrogen, progesterone, testosterone, etc.

We would intend to collaborate with other companies in the R&D and licensing of these products. They have already had discussions with a large number of companies who recognize the potential including Boots and Genta/Jago who are currently evaluating products. We know that Procter and Gamble, Bausch and Lomb, Pfizer, Sandoz, McNeil, Wyeth, Schering (Berlex), and Rhone Poulenc/ Dermick are currently seeking this type of technology.

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We would acquire the assets of this corporation and in the event limited research is required by Bentley we would consider spinning this company off into a shell corporation either formed by us or acquired so that we could raise funds independently in an off-balance sheet manner. Thereafter when the company becomes profitable, it would be re-acquired by Bentley in a stock swap. The reason for employing this strategy is to avoid the losses associated with basic R&D activities. This technique has been quite successful and commity used by Alza, Sepracor and Genzyme corporations.

Flemington Pharmaceuticals possess patented technology for rapid onset of therapeutics. The technology uses a bite capsule that delivers through the musocal membrane and the first products have been developed through Phase I. Since the applications involve products with an established history of safety and efficacy, the expense of development and the regulatory paths are minimal. They will be signing a major licensing agreement within the near future (60 days).

I have met with Flemington and there is interest in advancing the discussions to the next level since they are looking at the possibility of going public at this stage. The acquisition of Conrex technology will make Bentley a more interesting candidate because Flemington have also attempted to merge with Conrex over the past year believing there are a number of .

3. Fidia Pharmaceuticals is a sizable Italian company with annual revenues of approximately \$65 million. Acquisition of Fidia would result in additions to both our domestic and European operations including 870 patents on a worldwide basis, international distribution, a limited US presence but a number of pending US registrations, a tremendous opportunity to out-license a number of products.

The proforma financials have not yet been established but the basic assumption is that the combined companies would be profitable from the onset and a sufficient amount of capital would be in place to consummate the deal and continue the development of the R&D pipeline.

We envision a major change in R&D philosophy. To date, Fidia has individually funded all research electing to avoid licensing opportunities even though a number of sizable organizations have made offers to collaborate. By entering into R&D collaborations and licensing agreements they could save a tremendous amount of funds which would immediately be recognized as improvement in the bottom line.

	1996	1997	1998
Revenues w/ Fidia		90 mil	100 mil
Royalty income		2 mil	6 mil

4. Shire Pharmaceuticals Group Pic. is a growing U.K. company with revenues of approximately \$35 million. The company is profitable and has cash reserves of approximately \$40 million. The primary focus on the development, licensing and marketing of drugs in the specialty areas of metabolic bone diseases and the central nervous system.

Shire has hired The Wilkerson Group (div. of IBM) to find a merger candidate in the United States. Shire has its own sales force in the U.K. and Ireland and distributes through others in N. Africa, Mediterranean contries, middle and far east. The ideal merger candidate, as described to us, would be a U.S. based organization that is marginly profitable or at breakeven.

January 2, 1997

# Audit of the ETHYPHARM production site in Saragossa.

Date: December 10, 1996

#### Persons met:

#### Mateo GASCA

- Head of Quality Control, Manufacture and Encapsulation of the microgranules produced in the ETHYPHARM area
- Head of BELMAC Quality Control

#### ETHYPHARM representatives present:

- Adolfo de BASILIO
- Domingo BERNABE
- Pierre FONTANI

# Objective:

To check the compliance of the production carried out on behalf of ETHYPHARM on the BELMAC/ETHYPHARM site in Saragossa with the EEC GMP.

#### Programme:

Assessment of the follow-up to the quality actions reommended in M. GAVOILLE's report of 08.03.1996, following her audit visit on 13.02.1996.

Audit of the quality system applied to the ETHYPHARM microgranules manufacturing activity.

Progress of the quality points with reference to the assessment made by M. GAVOILLE on 13.02.1996.

# 1 - PRODUCTION PREMISES AND EQUIPMENT

None of the actions recommended for improving quality has been put into effect.

# 2 - DOCUMENTATION

# 2.1 - Technical documentation on MHB

Manufacture:

There are no official ETHYPHARM documents (critical defect). The operators work with documents proposed by ETHYPHARM France.

Control of Starting Materials, Intermediate Products and Finished Products: There are no official ETHYPHARM documents (critical defect). The documents used are BELMAC documents with UQUIFA methods and specifications.

# 2.2 - Quality Assurace Procedures

Only BELMAC procedures are used throughout the site.

In the ETHYPHARM manufacturing area, only a few record forms relating to ETHYPHARM procedures dating from 1992 are used. These procedures are kept in a filing box in the storage area (critical defect).

#### 2 - ORGANISATION

One and the same person, Mateo GASCA, is in charge of manufacture and control (critical defect),

# Audit of the ETHYPHARM production area

#### ① Warehouse - ETHYPHARM Intermediate Storage

The two conventional pans replaced by the GS are being kept temporarily in this room, and the storage of the materials is disorganised by the resultant clutter (major defect).

#### ② Weighing room

The 20-kg weight used for calibrating the balance is placed directly on the floor, with no particular protection (major defect).

#### ③ Conventional pan rooms

The rooms are not identified according to the activity pursued in them (major defect).

#### GS pan room

No production was under way, but the following items were present in the room:

- a sachet of microgranules with no label (microgranules stated to be MHB waste)
- plastic trays containing unidentified granules (stated to be neutral microgranules)
   (critical defect).

# Solution preparation room

This room is also used for storing production equipment.

A damaged sieve screen was present with the other screens, on the one and only sieve storage rack (critical defect).

A container labelled with only the words PVP 12 % was present in the room (critical defect).

# © Capsule filling room

At the end of the work day: the room was untidy and the surface of the machine covered with powder from the batch being manufactured (critical defect).

The thermohygrograph recording was not noted (4 tracings on the same sheet) (major defect).

# Washing room

At the end of the work day:

- the room was untidy and had not been cleaned or disinfected (critical defect).
- MHB microgranule waste was present in unlabelled sachets, placed directly on the floor (critical defect).

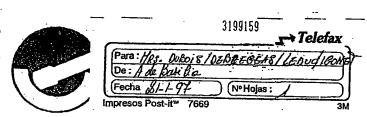
The equipment is incomplete:

- there is nowhere to put away the cleaning equipment and products.
- there is no sink suitable for cleaning the sieve screens. (critical defect).

#### CONCINISION

The degree of criticalness of the deviations from the EEC GMP shows that it will be necessary to implement the essential quality points in order to comply with European regulations.

Pierre FONTANI Quality Assurance Assistant



Fax 319 91 59 Telex: 2358I CENCO

A: CLEMENTE GONZALEZ (BELMAC) DE: ADOLFO DE BASILIO (ETHYPHARM)

Fecha: 20/1/97 Páginas: 1

Estimado Dr. González,

Hemos sido convocados por nuestra central para la toma de decisiones de los asuntos pendientes con BELMAC y para la presentación de los presupuestos 1997. Después de un largo debate, hemos llegado a las siguientes conclusiones:

A pesar del esfuerzo realizado recientemente por BELMAC para mejorar los rendimientos de fabricaciones y consecuentemente el costo para ETHYPHARM, éstos, según nuevos cálculos, siguen sin ser rentables para nuestro grupo.

Como ya hemos podido ver en la pasada reunión en Zaragoza, los márgenes de las fabricaciones de microgránulos de ETHYPHARM son reducidos. Estos márgenes de fabricación no son suficientemente altos para cubrir los costos facturados por BELMAC.

El deseo de ETHYPHARM ha sido fabricar toda la producción de la filial española en Zaragoza. BELMAC no dispone aún de una estructura GMP que permita exportar a determinados países. Las GMPs no han llegado al nivel requerido por algunos de nuestros clientes como hemos podido comprobar después de la visita de auditoria de HMR y la confirmación posterior de nuestro departamento de QA. Según este informe, el estatus GMP no cumple con la legislación española ni con las normas de la U.E.

La política de trabajo que se ha seguido hasta la fecha con BELMAC no ha sido la apropiada por lo que hemos decidido transferir las fabricaciones de los principios activos libres de patente a una de las fábricas del Grupo ETHYPHARM y parar la producción de omeprazol hasta que la situación de patentes nos permita fabricarlo en alguna de las fábricas de nuestro grupo.

El próximo día 23 de Enero, tendremos una reunión en Francia con UQUIFA en la que será debidamente informado sobre la situación actual.

Rogamos transmitan estas decisiones a su casa matriz en EEUU.

En espera de sus comentarios al respecto le saluda cordialmente,

dolfo de Basilio

TO: CLEMENTE GONZALEZ (BELMAC)

FROM: ADOLFO DE BASILIO (ETHYPHARM)

Date: 1/20/97

Dear Dr. Gonzalez,

We have been summoned by our mother company to take a decision regarding the pending matters with BELMAC and for the presentation of the 1997 budgets. After an extended debate, we have reached the following conclusions:

In spite of the effort recently made by BELMAC to improve the manufacturing productivity and consequently ETHYPHARM's cost, these, according to new estimates, are still not profitable for our group.

As we have already been able to see in the last meeting in Zaragoza, margins for the manufacturing of ETHYPHARM's microgranules are reduced. These manufacturing margins are not sufficiently high to cover the costs invoiced by BELMAC.

ETHYPHARM's desire has been to manufacture all the production of the Spanish branch in Zaragoza. BELMAC does not have yet a GMP structure that allows to export to specified countries. The GMPs have not reached the level required by some of our clients, as we have been able to verify after the audit of "HMR" and the later confirmation of our department of "QA." According to this report, the GMP status does not comply with the Spanish legislation nor with the E.U. norms.

The work policy that has been followed to date with BELMAC has not been the appropriate one, so that we have decided to transfer the manufacturing of our active principles free of patent to one of the factories of the ETHYPHARM Group, and to stop the production of omeprazol until the patents' situation allows us to manufacture it in one of the factories of our group. Next Januray 23rd, we will have a meeting in France with UQUIFA during which they will be properly informed of the present situation.

We ask you to transmit these decisions to your mother company in the U.S.

We are awaiting your commentaries on this matter.

Warm regards.

Adolph de Basilio

FACSIMILE TRANSMITTAL

Bentley Pharmaceuticals, Inc. One Urban Centre

Suite 548 4830 West Kennedy Blvd. Tampa, FL 33609-2517

Telephone (813) 286-4401 (813) 286-4402

To:

Patrice DeBregeas

Company:

Ethypharm

Fax #:

011 33 1 41 12 17 30

From:

James R. Murphy

Chairman & CEO

Date:

January 28, 1997

Subject:

Lab. Belmac Manufacturing for Ethypharm

Dear Patrice,

I am writing with regard to the fax that I received from your Spanish office. I am confused because, ever since I assumed control of Laboratorios Belmac, I have received nothing but extremely positive comments from your Spanish staff specifically, Sr. Basillo, who said: That the Belmac operation is now more efficient, more cooperative, more pleasant to work with, and beyond this he noted our high degree of sincerity and integrity.

Sr. Basilio's comments always were highly complimentary to me and our staff.

Even though Laboratorios Belmac has not received payment from Ethypharm in the past Year, we have continued to provide Ethypharm with product in a diligent and highly professional manner. Belmac's actions have documented our good faith, as well as confirmed our level of commitment and cooperation with your organization. Are you aware of any other company that would be as tolerant as Belmac has been? The amount of money overdue to date is approximately 60 million pesetas.

Also let me refresh your memory that we attempted in good faith, on numerous occasions, to establish a contractual relationship between our companies which Ethyphann declined to negotiate to conclusion.



CO191 T# 44 1.

Late Lands a removement

According to this fax, the Ethypharm renovated area does not comply with GMP requirements. Yet, Ethypharm has requested reimbursement based upon a claim that Ethypharm has spent money to bring the area into full compliance; further, Ethypharm management oversees the technology applications to manufactured products, therefore, it would seem illogical for Belmac to consider reimbursement for an area, that by your own admission, does not conform to GMP standards.

It appears that Ethypharm wants the luxury of a facility, personnel, export licenses, manufacturing license, administration, shipping, purchasing, etc., but without the costs or liabilities associated with the maintenance of personnel, facilities, employee indemnities, etc.

I suggest we schedule a meeting in Madrid to discuss the future of the relationship between our organizations and on the agenda we will be prepared to discuss:

- · Arrangements to receive payments that are long overdue
- Belmac's proposal for a structure that would provide a profitable operation for Ethypharm in Spain.
- Obtain an understanding of what problems (if any) exist since I have only heard compliments from Ethypharm.
- And if you wish, discuss the orderly departure of Ethypharm from the Belmac facilities.

I suggest the following people be in attendance during the first part of Feb.:

Ethyoharm

Lab. Belmac

Patrice DeBregeas Adolpho Basilio

Jim Murphy Clemente Gonzolas

Dr. Monterde Mateo Gazca

Best Regards,

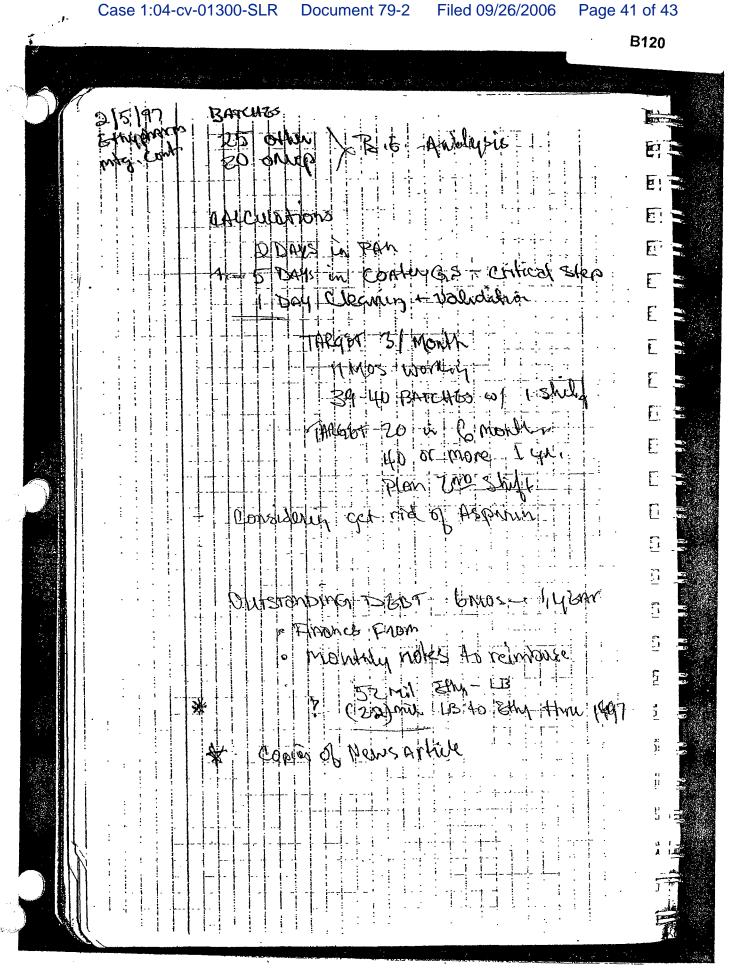
Jim

Document 79-2

Filed 09/26/2006

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Case 1:04-cv-01300-SLR



#### RAPPORT DE REUNION

Philadelphie, 05 février 1997

#### Bentley - Belmac

Bentley-Belmac:

Mr. J. Murphy

Ethypharm:

CD

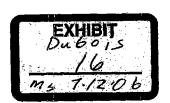
#### I - Problème Belmac Espagne

- J. Murphy a prétendu ne pas avoir été au courant de la situation avant notre lettre du 20/01/97, c'est plausible. J'ai donc refait l'historique, en particulier depuis la réunion du 10 octobre 1996:
- \* Seul le MHB justifie l'existence d'une fabrication Ethypharm en Espagne.
- \* Vingt lots annuels de MHB sont nécessaires à l'équilibre des comptes aux conditions actuelles, en plus de 23 à 25 lots d'autres produits (Aspirine, Piroxicam, Indométacine). Nous devons faire un minimum de 40 lots de MHB pour honorer nos commandes et faire un profit raisonnable.
- \* Entre notre rapport d'audit qualité de début 1996 et celui de début 1997, aucune amélioration n'a été entreprise. Les installations ne sont pas en cause, mais les procédures, la formation du personnel à la qualité, l'organisation et les GMP ne sont pas respectés.
- \* Il a été impossible de trouver un accord sur un nouveau contrat de fabrication compte-tenu des demandes de Belmac. Nos 40 millions de pesetas procurent un profit à Belmac, alors que pour nous la perte existe jusqu'à une fabrication de 20 lots MHB + 25 autres produits.

Dans un premier temps, J. Murphy a proposé que Belmac reprenne toutes nos activités en Espagne et fabrique et vende pour nous. Je lui ai fait la proposition suivante :

- Nous devons être certains qu'ils peuvent fabriquer 40 lots de MHB et qu'ils peuvent se mettre au niveau GMP.
- 20 lots de MHB doivent être fabriqués avant l'été et l'amélioration des GMP largement entamée. Dans ce cas, nous maintenons le loyer de 40 millions de pesetas par an, soit

Les loyers en retard seront payés sur l'année (Belmac souhaite des traîtes pour pouvoir les escompter), déduction faite des sommes restantes dues pour Belmac.



Si tout se déroule comme prévu, nous ferons une proposition de "fee per MHB batch", à partir de 20 jusqu'à 40. D'après nos calculs, les 40 lots peuvent être fabriqués avec une seule équipe. Ce supplément devrait toutefois permettre de couvrir le coût supplémentaire de la 2ème équipe (2 personnes) nécessaire au delà de 40 lots.

J'envoie à J. Murphy la traduction anglaise du rapport d'assurance qualité, ainsi qu'une confirmation écrite de notre proposition. J. Murphy en discute immédiatement avec C. Gonzales et sera en Europe dans 2/3 semaines. Bentley-Belmac dispose d'un consultant qualité (ex SKB) pour toutes ses fabrications. Il n'a pas encore été à Saragosse, mais devrait s'y rendre très prochainement.

# II - Autres

Bentley serait sur le point d'acheter une compagnie aux USA, disposant d'une usine neuve GMP, d'une force de vente et d'un portefeuille de produits dont une vingtaine seraient intéressants (génériques ou branded?). Nous en saurons plus dans un mois, J. Murphy faisait un tour pour récolter l'argent nécessaire auprès d'investisseurs (Boston, NY, Philadelphie), et a priori il l'aurait trouvé!

Belmac a acquis pour l'Espagne des nouveaux produits :

Test diagnostic pour H. Pylori (très simple, sanguin) et diagnostic pour la présence de sang dans les fèces (papier test à jeter dans les toilettes avant de tirer la chasse!). L'origine de ces tests est Biomerica.

Une nouvelle forme d'Erythromycine (Biolid) va être mise au point avec l'Université d'Iowa (en voie d'approbation FDA).

Bentley cherche un licencié aux US. Ils travaillent beaucoup sur les gels transdermiques (Diclofénac, Isosorbide 6).

La presse Espagnole s'est faite l'écho des améliorations réalisées par Belmac à Saragosse. C'est dans ce cadre qu'un reportage T.V. a été réalisé, J. Murphy ne sait pas quand il passera.